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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/492,709	01/27/2000	Judith Zyskind	ELITRA.001A	1266

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KNOBBE MARTENS OLSON & BEAR LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

28

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/492,709

Applicant(s)  
Zyskind et al.

Examiner  
Ardin Marschel

Art Unit  
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 22, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-99 and 102-118 is/are pending in the application.
- 4a) Of the above, claim(s) 1-34, 45-67, 78, 80-84, 94, 95, 97, and 102-111 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35, 34-44, 68, 79, 85-93, 96, 98, 99, and 112-118 is/are rejected.
- 7) ☒ Claim(s) 100 and 101 have been canceled. ~~is/are rejected.~~
- 8) ☒ Claims 1-99 and 102-118 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No. 23
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No. (5 sheets) 6) ☐ Other:

Applicants' arguments, filed 8/22/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

In view of the papers, filed 8/22/02 (Paper No. 26), as a correction of inventorship under 37 CFR § 1.48(b), the inventorship of this nonprovisional application has been changed by the deletion of KARI L. OHLSEN, JOHN TRAWICK, JAMIE M. FROELICH, GRANT J. CARR, ROBERT T. YAMAMOTO, and HOWARD H. XU.

In the REMARKS, filed 8/22/02, on page 5 applicants made a statement that they believed that claims 45, 80-93, and 97 have been withdrawn and that the statement of pending claims is in error as stated on the Office action, apparently the Office action, mailed 5/6/02. Applicants then stated that a correction should be made to include claims 45, 80-83, and 97 as pending. In response, these remarks are not understood in that all of claims 1-99 and 102-110 remain pending in the instant application as well as newly submitted claims 111-118. Only claims 100 and 101 have been canceled as of the mailing of this office action. Within this set of 116 claims, a restriction requirement with a specie election has been applied and responded to by applicants. The elections from said restriction and specie election resulted

in withdrawal from examination of claims drawn to non-elected subject matter. The remaining claims, drawn to elected subject matter are still deemed properly to be claims 34-44, 68-77, 79, 85-93, 96, 98, 99, with newly added claims 112-118. The elected subject matter is drawn to methods of identifying compounds based on sensitized cell vs. nonsensitized cell growth inhibition wherein the specie of gene product being inhibited is polypeptide gene product activity. Consideration of claim 45 reveals that it is directed to gene product activity inhibition which is non-elected RNA subject matter and is properly withdrawn from examination. Claims 80-83 and 97 (and newly submitted claim 111) are drawn to antisense nucleic acid inhibition which is reasonably interpreted as inhibition of RNA translation which also in non-elected subject matter. Thus, claims 45, 80-83, 97, and 111 remain as pending claims, but are withdrawn from consideration due to being directed to non-elected subject matter. In summary, claims 1-99 and 102-118 are instantly pending claims and claims 35-44, 68-77, 79, 85-93, 96, 98, 99, and 112-118 are under examination with the remainder of the instantly pending claims being withdrawn from consideration.

The restriction/election requirements are still deemed proper and are therefore made FINAL.

MEW MATTER REJECTION:

Claims 114-118 are rejected under 35 U.S.C. § 112, first

paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 114-118 add NEW MATTER via the added limitations directed to "candidate compound" being "a natural product extract". Written basis for this type of candidate compound as utilized in the instant invention has not been found as filed. These limitations therefore are NEW MATTER.

#### VAGUENESS AND INDEFINITENESS REJECTION:

Claims 35-44, 85-93, 96, 98, 99, 112-114, 117, and 118 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that the instant claims have been amended in the preamble, such as in claim 35, to indicate that a candidate compound is not previously known to possess cell proliferation ability, but that this has not been added as an active claim step. Thus, two possible conflicting interpretations to the claims are that 1) references which disclose only the active claim steps may be prior art and 2) the preamble wording must be included in a reference for it to be prior art against such claims. Clarification via clearer claim wording is requested.

## REJECTION BASED ON PRIOR ART:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 68, 79, 96, 98, 112, 113, 115, 116, and 118 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Gucev et al. [Cancer Research 56(7):1545(1996)].

Gucev et al. performs a number of tests wherein antisense or sense oligonucleotides (ODNs) are added to cells along with candidate compounds for interaction with IGFBP-3 such as Retinoic acid or TGF- $\beta$ 2. These tests were performed as disclosed on page 1547, starting in the lefthand column, line 9, through page 1548, lefthand column, line 5. The determining of the effect of the candidate compounds compared between antisense and sense ODN inhibition is included. It is acknowledged that Retinoic acid as well as TGF- $\beta$ 2 are noted in the abstract as being inhibitory of cell proliferation. As noted in the above 112, second paragraph, rejection that a possible interpretation of a claim is that a reference which anticipates the actual active claim steps albeit without citing preamble practices properly anticipates the

claims.

Claims 69-77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example the specification at page 19, line 25. Applicants are requested to review the entirety of the specification for such codes. Applicants are required to delete the embedded hyperlink and/or other browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

December 20, 2002

*Andin U. Marschel*  
ANDIN U. MARSCHEL  
FEDERAL BUREAU OF INVESTIGATION